Boston Scientific

K063493

# 510(k) Summary of Safety and Effectiveness

## Boston Scientific Corporation

## iLab™ Ultrasound Imaging System with iReview™ Software

DEC 2 1 2006

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| Submitted By | Boston Scientific Corporation<br>49700 Bayside Parkway<br>Fremont, CA 94538 |
| Contact Person | Christine Dunbar<br>Principal Regulatory Affairs Specialist<br>Tel: (510) 624-2461<br>Fax: (510) 624-2569<br>christine.dunbar@bsci.com |
| Date Prepared | November 17, 2006 |
| Proprietary Name | iReview™ Software |
| Common Name(s) | (Accessory To) Ultrasound Diagnostic Imaging System<br>Ultrasonic Pulsed Doppler Imaging System (90IYN)<br>Ultrasonic Pulsed Echo Imaging System (90IYO) |
| Classification Name(s) | 21 CFR Part 892.1550 (90IYN) Ultrasonic Pulsed Doppler Imaging System<br>21 CFR Part 892.1560 (90IYO) Ultrasonic Pulsed Echo Imaging System |
| Predicate Device | The iReview Software accessory to the iLab™ Ultrasound Imaging System is substantially equivalent to the following device: |

| Product | 510(k) | Clearance Date |
|---|---|---|
| iLab™ Intravascular Ultrasound System | K051579 | July 14, 2005 |

Description of the Device

The iLab™ Ultrasound Imaging System with the iReview™ Software accessory, is designed for real-time viewing of intravascular anatomies and is intended to be a basic diagnostic tool for imaging and evaluation of patients who are candidates for transluminal procedures.

The iLab™ System with the iReview Software accessory consists of two compact PC units (one for Image Processing and one for Data Acquisition), up to two displays (one primary and an optional secondary) and the iReview Software contained on a separate CD. The iReview Software utility can be installed on any commercial grade PC that meets the minimum hardware and operating system requirements. The iLab System imaging and processing PC are used during an intravascular

procedure, at the end of the IVUS procedure, the processing PC supports the archiving of the images obtained during the procedure. The iLab System processing PC converts the native iLab images into DICOM format images prior to archiving to removal media such as a CD, DVD or removable hard disk cartridge. Images can also be archived to a DICOM network server.

The iReview™ Software utility enables the off-line review of the archived iLab System images, including the Longview™ reconstructed images, Dynamic Review™ of the IVUS image runs, area and distance measurements, book marked images, image graphics, bio-signals such as ECG and the broadcast of any audio recording acquired during the IVUS procedure. The iReview Software also supports the creation of new area and distance measurements and the ability to export images to external printers. The iReview Software utility, using the iLab proprietary GUI look and feel, is a simple easy to use, image viewing software for iLab IVUS images.

Intended Use/Indications

The iLab™ Ultrasound Imaging System is intended for ultrasound examinations of intravascular pathology. Intravascular ultrasound is indicated in patients who are candidates for transluminal interventional procedures such as angioplasty and atherectomy.

The iReview Software utility, as an accessory to the iLab Ultrasound Imaging System, does not change the indications for use or the intended use of the parent device.

Device Technology Characteristics and Comparison to Predicate Device

The iReview™ Software is based on the software architecture of the previously cleared iLab™ software (K051679) and allows for a standard graphical user interface between iLab and iReview. Uniform and consistent applications increase efficiency by utilizing this standardized graphical user interface and software applications.

*Bench Testing*

Bench testing was performed to evaluate the performance and functionality of the iReview™ Software utility as installed on several PC Laptop and Desktop systems. All testable requirements in the Marketing and Product Requirements Specifications have been verified. The installation of the iReview Software utility on a consumer grade PC hardware that meets the minimum system requirements, and has been shown to be effective for the display of iLab™ System archived images.

*Non-clinical Test Results*

Software unit and system level verification testing demonstrate that the software utility meets the acceptance criteria as noted in the iReview™ Software Unit and System Test Plans located in

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Attachment VII. All requirements in the Software Requirements Specifications have been verified by the system level testing.

All software risk mitigations determined by the FMEA have been verified to be effective and demonstrate that the iReview™ Software utility meets all product and marketing requirements. It is the belief of Boston Scientific Corporation that the iReview Software utility is safe and effective for its use as an accessory to the iLab™ System, for the purpose of supporting the review of iLab System's archived images.

*Software Verification Testing*

The iReview Software utility has been fully verified and validated in accordance with applicable FDA guidance documents. This testing includes software verification testing performed on multiple configurations of PC systems by skilled software testers. The results demonstrate that the iReview Software utility satisfies all Product and Marketing requirements for its intended purpose as a safe and effective software utility for the post-procedural display of iLab™ Ultrasound Imaging System archived images.

*Software Validation Testing*

The iReview Software utility validation effort has been performed by testers with iLab clinical experience on PC systems that are production equivalent and meet the minimum system requirements. The iReview Software utility has been validated to meet the user needs and intended uses. The validation results summary report in progress at the time of this submission. All plans, test results and summary reports will be retained in the Design History File for the iReview™ Software project.

Conclusion

The iLab™ Ultrasound Imaging System with the iReview Software utility, contains the same fundamental technology, has similar technical characteristics (i.e. GUI and software functions and has the same intended use as the predicate device, the iLab™ Ultrasound Imaging System.

It is the belief of Boston Scientific that the design verification tests support a determination that the iReview Software utility, as an accessory to the iLab System, is safe and effective and the iLab Ultrasound Imaging System with the iReview Software utility is substantially equivalent to the predicate iLab System device (K051679).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 1 2006

Boston Scientific Corporation
Ms. Christine Dunbar
Principal Regulatory Affairs Specialist
IVUS Technology Center
47900 Bayside Parkway
Fremont, CA 94538

Re: K063493
Trade Name: iReview™ Software Accessory to iLab™
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II (two)
Product Code: IYN
Dated: November 17, 2006
Received: November 20, 2006

Dear Ms. Dunbar:

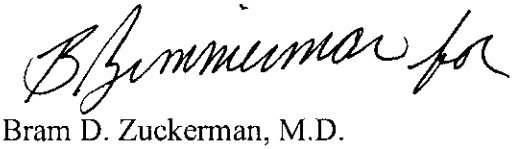
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Boston Scientific

# Indications for Use Statement

**510(k) Number:**

**Device Name:** iReview™ Software, an accessory to the iLab™ Ultrasound Imaging System

**Indications for Use:** The iLab™ Ultrasound Imaging System is intended for ultrasound examinations of intravascular pathology. Intravascular ultrasound is indicated in patients who are candidates for transluminal interventional procedures such as angioplasty and atherectomy.

The iReview Software accessory does not change the iLab indications for use.

Prescription Use ___X___ AND/ OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number: K043493